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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/816,768

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Hermann Oppermann

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EXAMINER

LI, RUIXIANG

ART UNIT

PAPER NUMBER

1646

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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31 DAYS

01/12/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/816,768

Applicant(s)

OPPERMANN ET AL.

Examiner

Ruixiang Li

Art Unit

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-19 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

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DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-5, to the extent that they are drawn to a biologically active TGF- β family member fusion protein comprising a heterologous tissue targeting domain that binds to a cell surface molecule on an osteoprogenitor cell, classified in class 530, subclass 350.
 - II. Claims 1-5, to the extent that they are drawn to a biologically active TGF- β family member fusion protein comprising a heterologous tissue targeting domain that binds to a cell surface molecule on a chondrocyte, classified in class 530, subclass 350.
 - III. Claims 1-5, to the extent that they are drawn to a biologically active TGF- β family member fusion protein comprising a molecular targeting domain, classified in class 530, subclass 350.
 - IV. Claims 1-5, to the extent that they are drawn to a biologically active TGF- β family member fusion protein comprising a heterologous metal binding domain, classified in class 530, subclass 350.

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- V. Claims 1-5, to the extent that they are drawn to a biologically active TGF- β family member fusion protein comprising a heterologous protein binding domain, classified in class 530, subclass 350.
- VI. Claims 1-5, to the extent that they are drawn to a biologically active TGF- β family member fusion protein comprising a heterologous ceramic binding domain, classified in class 530, subclass 350.
- VII. Claims 1-5, to the extent that they are drawn to a biologically active TGF- β family member fusion protein comprising a heterologous HAP binding domain, classified in class 530, subclass 350.
- VIII. Claims 1-5, to the extent that they are drawn to a biologically active TGF- β family member fusion protein comprising a heterologous collagen domain, classified in class 530, subclass 350.
- IX. Claims 6-8, to the extent that they are drawn to a latent TGF- β family member comprising a cleavable leader sequence, classified in class 530, subclass 350.
- X. Claims 6-9, to the extent that they are drawn to a latent TGF- β family member comprising a heterologous cleavable leader sequence, classified in class 530, subclass 350.

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- XI. Claims 10-16, to the extent that they are drawn to a biologically active TGF- β family member comprising a truncated leader sequence, classified in class 530, subclass 350.
- XII. Claim 17, to the extent that it is drawn to a biologically active heterodimer of TGF- β family member proteins comprising a first subunit being a TGF- β family member fusion protein, and a second subunit comprising a TGF- β family member fusion protein different from that of the first subunit, classified in class 530, subclass 350.
- XIII. Claims 17, 18, to the extent that they are drawn to a biologically active heterodimer of TGF- β family member proteins comprising a first subunit being a TGF- β family member fusion protein, and a second subunit comprising a wild type TGF- β 1 subunit, classified in class 530, subclass 350.
- XIV. Claims 17, 18, to the extent that they are drawn to a biologically active heterodimer of TGF- β family member proteins comprising a first subunit being a TGF- β family member fusion protein, and a second subunit comprising a wild type TGF- β 2 subunit, classified in class 530, subclass 350.
- XV. Claims 17, 18, to the extent that they are drawn to a biologically active heterodimer of TGF- β family member proteins comprising a first subunit being a

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TGF- β family member fusion protein, and a second subunit comprising a wild type TGF- β 3 subunit, classified in class 530, subclass 350.

XVI. Claims 17, 18, to the extent that they are drawn to a biologically active heterodimer of TGF- β family member proteins comprising a first subunit being a TGF- β family member fusion protein, and a second subunit comprising a wild type TGF- β 4 subunit, classified in class 530, subclass 350.

XVII. Claims 17, 18, to the extent that they are drawn to a biologically active heterodimer of TGF- β family member proteins comprising a first subunit being a TGF- β family member fusion protein, and a second subunit comprising a wild type TGF- β 5 subunit, classified in class 530, subclass 350.

XVIII. Claims 17, 18, to the extent that they are drawn to a biologically active heterodimer of TGF- β family member proteins comprising a first subunit being a TGF- β family member fusion protein, and a second subunit comprising a wild type dpp subunit, classified in class 530, subclass 350.

XIX. Claims 17, 18, to the extent that they are drawn to a biologically active heterodimer of TGF- β family member proteins comprising a first subunit being a TGF- β family member fusion protein, and a second subunit comprising a wild type Vg-1 subunit, classified in class 530, subclass 350.

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- XX. Claims 17, 18, to the extent that they are drawn to a biologically active heterodimer of TGF- β family member proteins comprising a first subunit being a TGF- β family member fusion protein, and a second subunit comprising a wild type Vgr-1 subunit, classified in class 530, subclass 350.
- XXI. Claims 17, 18, to the extent that they are drawn to a biologically active heterodimer of TGF- β family member proteins comprising a first subunit being a TGF- β family member fusion protein, and a second subunit comprising a wild type 60A subunit, classified in class 530, subclass 350.
- XXII. Claims 17, 18, to the extent that they are drawn to a biologically active heterodimer of TGF- β family member proteins comprising a first subunit being a TGF- β family member fusion protein, and a second subunit comprising a wild type BMP-2A subunit, classified in class 530, subclass 350.
- XXIII. Claims 17, 18, to the extent that they are drawn to a biologically active heterodimer of TGF- β family member proteins comprising a first subunit being a TGF- β family member fusion protein, and a second subunit comprising a wild type BMP-3 subunit, classified in class 530, subclass 350.
- XXIV. Claims 17, 18, to the extent that they are drawn to a biologically active heterodimer of TGF- β family member proteins comprising a first subunit being a TGF- β family member fusion protein, and a second subunit

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comprising a wild type BMP-4 subunit, classified in class 530,
subclass 350.

XXV. Claims 17, 18, to the extent that they are drawn to a biologically active heterodimer of TGF- β family member proteins comprising a first subunit being a TGF- β family member fusion protein, and a second subunit comprising a wild type BMP-5 subunit, classified in class 530, subclass 350.

XXVI. Claims 17, 18, to the extent that they are drawn to a biologically active heterodimer of TGF- β family member proteins comprising a first subunit being a TGF- β family member fusion protein, and a second subunit comprising a wild type BMP-6 subunit, classified in class 530, subclass 350.

XXVII. Claims 17, 18, to the extent that they are drawn to a biologically active heterodimer of TGF- β family member proteins comprising a first subunit being a TGF- β family member fusion protein, and a second subunit comprising a wild type Dorsalin subunit, classified in class 530, subclass 350.

XXVIII. Claims 17, 18, to the extent that they are drawn to a biologically active heterodimer of TGF- β family member proteins comprising a first subunit

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being a TGF- β family member fusion protein, and a second subunit comprising a wild type OP-1 subunit, classified in class 530, subclass 350.

XXIX. Claims 17, 18, to the extent that they are drawn to a biologically active heterodimer of TGF- β family member proteins comprising a first subunit being a TGF- β family member fusion protein, and a second subunit comprising a wild type OP-2 subunit, classified in class 530, subclass 350.

XXX. Claims 17, 18, to the extent that they are drawn to a biologically active heterodimer of TGF- β family member proteins comprising a first subunit being a TGF- β family member fusion protein, and a second subunit comprising a wild type OP-3 subunit, classified in class 530, subclass 350.

XXXI. Claims 17, 18, to the extent that they are drawn to a biologically active heterodimer of TGF- β family member proteins comprising a first subunit being a TGF- β family member fusion protein, and a second subunit comprising a wild type GDF-1 subunit, classified in class 530, subclass 350.

XXXII. Claims 17, 18, to the extent that they are drawn to a biologically active heterodimer of TGF- β family member proteins comprising a first subunit being a TGF- β family member fusion protein, and a second subunit comprising a wild type GDF-3 subunit, classified in class 530, subclass 350.

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- XXXIII. Claims 17, 18, to the extent that they are drawn to a biologically active heterodimer of TGF- β family member proteins comprising a first subunit being a TGF- β family member fusion protein, and a second subunit comprising a wild type GDF-9 subunit, classified in class 530, subclass 350.
- XXXIV. Claims 17, 18, to the extent that they are drawn to a biologically active heterodimer of TGF- β family member proteins comprising a first subunit being a TGF- β family member fusion protein, and a second subunit comprising a wild type Inhibin α subunit, classified in class 530, subclass 350.
- XXXIV. Claims 17, 18, to the extent that they are drawn to a biologically active heterodimer of TGF- β family member proteins comprising a first subunit being a TGF- β family member fusion protein, and a second subunit comprising a wild type Inhibin β A subunit, classified in class 530, subclass 350.
- XXXV. Claims 17, 18, to the extent that they are drawn to a biologically active heterodimer of TGF- β family member proteins comprising a first subunit being a TGF- β family member fusion protein, and a second subunit comprising a wild type Inhibin β B subunit, classified in class 530, subclass 350.

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XXXVI. Claim 19, a method of purifying a heterodimer of TGF- β family proteins, classified in class 530, subclass 412.

2. The inventions are distinct, each from the other because of the following reasons:
3. The following pairwise combinations of products are independent and distinct, wherein neither member of a pair is required for the production or use of the other, and wherein each of the pair can be manufactured independently of the other and used for independent and distinct purposes: I and each of II-XXXV; II and each of III-XXXV; III and each of IV-XXXV; IV and each of V-XXXV; V and each of VI-XXXV; VI and each of VII-XXXV; VII and each of VIII-XXXV; VIII and each of IX-XXXV; IX and each of X-XXXV; X and each of XI-XXXV; XI and each of XII-XXXV; XII and each of XIII-XXXV; XIII and each of XIV-XXXV; XIV and each of XV-XXXV; XV and each of XVI-XXXV; XVI and each of XVII-XXXV; XVII and each of XVIII-XXXV; XVIII and each of XIX-XXXV; XIX and each of XX-XXXV; XX and each of XXI-XXXV; XXI and each of XXII-XXXV; XXII and each of XXIII-XXXV; XXIII and each of XXIV-XXXV; XXIV and each of XXV-XXXV; XXV and each of XXVI-XXXV; XXVI and each of XXVII-XXXV; XXVII and each of XXVIII-XXXV; XXVIII and each of XXIX-XXXV; XXIX and each of XXX-XXXV; XXX and each of XXXI-XXXV; XXXI and each of XXXII-XXXV; XXXII and each of XXXIII-XXXV; XXXIV and each of XXXV.
4. Inventions XXXVI and each of I-XXXV are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruixiang Li whose telephone number is (571) 272-0875. The examiner can normally be reached on Monday through Friday from 8:30 am to 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, can be reached on (571) 272-0835. The fax number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, please contact the Electronic Business Center (EBC) at the toll-free phone number 866-217-9197.


Ruixiang Li, Ph.D.
Primary Examiner
January 4, 2007

RUIXIANG LI, PH.D.
PRIMARY EXAMINER